

REMARKS

This Amendment is filed in response to the Office Action dated May 5, 2005, accompanied by an extension of time filed within the five-month time period for response, which time period is set to expire on October 5, 2005. Reconsideration of this application is requested in view of the foregoing amendments and the following remarks.

Before this amendment, claims 1-15 were pending. Claims 1-15 were rejected in the Office Action dated May 5, 2005. In this amendment and response, Claims 1, 3, 5, and 9-15 were amended. Claims 2, 4, 7 and 8 are cancelled. Claim 6 is as originally filed. Now claims 1, 3, 5, 6 and 9-15 are pending.

Support for the amendment to claim 1 is found on page 8, paragraph 21 and example one beginning on page 12, paragraph 29. Other amendments to the claims address formalities are not substantive. Applicants assert that no new matter has been added by these amendments.

Claim Rejection 35 U.S.C. § 112

The Examiner rejected claims 4 and 7 under 35 U.S.C. § 112 as failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner asserts that the use of trademark/trade names in claims 4 and 7 render the claims indefinite. Applicant has cancelled these claims. This rejection is now moot.

Claim Rejection 25 U.S.C. § 102

The Examiner rejected claims 1-2, 5, 8-9, and 15 under 35 U.S.C. § 102(e) as being anticipated by US Patent Number 6,841,168 ("Worrall"). Applicant respectfully traverses this rejection so far as it pertains to the presently amended claims. Worrall teaches a method for the preservation of biologically active material. Examples of lyophilized biologically active material include viruses, proteins and nucleic acids. The problem addressed in Worrall is the preservation

of solid lyophilized biological material for long periods of time without requiring refrigeration. *See*, Worrall at column 1, lines 31-60.

Worrall characterizes the invention as follows:

The present invention is primarily concerned with a method of preserving biologically active material using chitosan and trehalose under conditions which cause water to be removed while, at the same time, allowing the biological integrity of the material to be maintained. (Worrall at column 2, lines 20-24).

Worrall does not teach a quaternized ammonium cationic polysaccharide. The chitosan polysaccharide disclosed in Worrall is a primary amine.

Furthermore, Worrall does not teach an aqueous ophthalmic solution as set forth in claim 1. The material being preserved in Worrall is a lyophilized or dehydrated mixture. While it is true that the mixture is hydrated, there is no teaching in Worrall that addresses the preservative effect on the hydrated biologically active composition. Thus, the preservation is not taught to work in an aqueous solution. Furthermore, there is no indication that the resulting rehydrated composition is formulated to be compatible for use in a patient's eye.

Applicant respectfully asserts that Worrall does not anticipate claim 1 as currently amended as well as claims 3, 5, 6 and 9-15, which depend from claim 1. Withdrawal of this rejection is requested.

Claim Rejection 35 U.S.C. § 103

The Examiner rejected claims 3-4, 6-7, 10-12 and 14 under 35 U.S.C. § 103 as being unpatentable over Worrall in view of US patent number 4,767,463 ("Brode"). Applicant appreciates the Examiner's acknowledgement that Worrall fails to teach using variations of polyquaternium-10 and respectfully traverses this rejection. As noted above, Worrall does not teach the use of a quaternium

ammonium polysaccharide. Worrall does not teach an ophthalmic solution. Furthermore, Worrall does not teach an amount effective for solution preservation of an aqueous solution.

Brode teaches a combination of glycosaminoglycan and a certain cationic polymer as properties of substantivity to keratinous material, compatibility, stability, humectancy, rheology and other properties useful in personal or medical applications (*see*, Brode Abstract). Brode does not teach that the quaternized ammonium cationic polysaccharide is present in an amount effective to preserve the solution.

Brode teaches a wide variety of Kericare products (i.e., treatment of keratinaceous materials). However, no disclosure is made of ophthalmic formulations. The present invention is directed to an aqueous ophthalmic solution. Thus, Brode does not overcome the deficiencies of Worrall as it pertains to newly amended claim 1 and presently pending dependent claims 3, 6, 10-12 and 14.

The office action rejected claim 13 as being unpatenable over Worrall in view of US patent number 5,658,915 ("Abe"). Abe discloses a polyelectrolyte complex. Describing the invention, Abe states that a polyelectrolyte complex can be formed "by mixing a solution of a cationic polymer (a polyelectrolyte having a positive charge) and a solution of an anionic polymer (a polyelectrolyte having negative charges)." Thus, the subject of Abe is not a cationic polysaccharide but a complex of a cationic polymers and an anionic polymer.

The polyelectrolyte complex disclosed in Abe is different from quaternium or quaternized ammonium cationic polysaccharide in the present invention. Moreover, the polyelectrolyte complex "may be dissolved in a particular three component solvent (for example, water/acetone/low molecular weight salt with a particular composition), but is insoluble in a general solvent." Acetone is not a solvent that is compatible with the tissue of the eye. Thus, the solution taught in Abe is not an "ophthalmic solution." Additionally, the complex taught in Abe is


insoluble in water. Insoluble preservatives are incompatible in ophthalmic solutions. Abe does not teach an ophthalmic solutions.

Applicant assures that no prior art teaches an ophthalmic solution that is preserved by a quaternized ammonium cationic polysaccharide in an amount effective for solution preservation. Data in the application supports its patentability. Each of the solutions tested passed the microbial preservative efficacy test. Never before has an ophthalmic solution been preserved with quaternized ammonium cationic polysaccharide. The present invention demonstrates that this class of compounds known to be gentle can be used in the present function. This technological development represents a significant improvement in the state of the art. Applicant believes that the present application is in condition for an allowance and respectfully requests allowance of the same.

No additional fee is believed to be due. However, please charge any additional fees or credit overpayment to Deposit Account No. 02-1425.

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Respectfully submitted,



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